

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF ALABAMA  
NORTHERN DIVISION

CAROLYN ROLLINS and LESTER  
ROLLINS,

Plaintiffs,

v.

BAYER CORPORATION,

Defendant.

)  
)  
)  
)  
)  
)  
)  
)  
)  
)  
)

CIVIL ACTION NUMBER:  
2:05-cv-00452-MHT-SRW

**ANSWER OF DEFENDANT BAYER CORPORATION TO PLAINTIFFS'**  
**AMENDMENT TO COMPLAINT**

COMES NOW Defendant BAYER CORPORATION (hereinafter referred to as "Bayer") and answers Plaintiffs' unverified Amendment to Complaint, served on Bayer and for the same would show the Court as follows:

1. In answer to paragraph 1, Bayer admits this Court has subject matter jurisdiction. Although Bayer denies any implication that Plaintiffs may be entitled to recover the same, Bayer admits that, upon information and belief, the amount in controversy exceeds \$75,000 and that complete diversity of citizenship between Plaintiffs and Defendant exists.

2. In answer to paragraph 2, Bayer states that no allegation in paragraph 2 is directed at Bayer and, therefore, no answer is required by Bayer. To the extent a response by Bayer may be deemed necessary, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of the allegations asserted and therefore denies the allegations contained therein.

3. In answer to paragraph 3, Bayer states that no allegation in paragraph 3 is directed at Bayer and, therefore, no answer is required by Bayer. To the extent a response by Bayer may be deemed necessary, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of the allegations asserted and therefore denies the allegations contained therein.

4. In answer to paragraph 4, Bayer admits that it is an Indiana corporation with its principal place of business in Pittsburgh, Pennsylvania. Bayer further admits that prior to November 6, 2000, it manufactured, promoted, marketed and sold non-prescription, over-the-counter medicines containing PPA for use in accordance with their labeling in Alabama and throughout the United States under the *Alka-Seltzer Plus* effervescent cold medicine brand name. Except as admitted, Bayer denies the allegations contained in paragraph 4.

5. In answer to paragraph 5, Bayer admits that prior to November 6, 2000, it manufactured, promoted, marketed and sold non-prescription, over-the-counter medicines containing PPA for use in accordance with their labeling in Alabama and throughout the United States under the *Alka-Seltzer Plus* effervescent cold medicine brand name. Except as admitted, Bayer denies the allegations contained in paragraph 5.

6. In answer to paragraph 6, Bayer states that paragraph 6 contains no allegations directed at Bayer and, therefore, no answer is required by Bayer. To the extent a response by Bayer is deemed necessary, Bayer admits that PPA is a chemical and that it is a member of a class of substances known as sympathomimetic amines. Except as admitted, Bayer denies the remaining allegations.

7. In answer to paragraph 7, Bayer admits that prior to November 6, 2000, it manufactured, promoted, marketed and sold non-prescription, over-the-counter medicines containing PPA for use in accordance with their labeling under the *Alka-Seltzer Plus* effervescent cold medicine brand name. Except as admitted, Bayer denies the remaining allegations.

8. In answer to paragraph 8, Bayer states that paragraph 8 contains no allegations directed at Bayer and, therefore, no answer is required by Bayer. To the extent an answer by Bayer is deemed necessary, Bayer denies the allegations contained therein.

9. In answer to paragraph 9, Bayer states that paragraph 9 contains no allegations directed at Bayer and, therefore, no answer is required by Bayer. To the extent an answer by Bayer is deemed necessary, Bayer admits that PPA is a vasoconstrictor and was an active ingredient in over-the-counter decongestant medicines and appetite suppressants. As to the remaining allegations, Bayer lacks knowledge and information sufficient to form a belief as to the truth of the allegations asserted and therefore denies the allegations contained therein.

10. In answer to paragraph 10, Bayer states that the allegations concerning FDA's actions state legal conclusions to which no response is required by Bayer. To the extent the allegations concerning FDA's actions require a response, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of such allegations and therefore denies the allegations contained therein.

11. In answer to paragraph 11, Bayer states that the allegations concerning FDA's actions state legal conclusions to which no response is required by Bayer. To the extent the allegations concerning FDA's actions require a response, Bayer states that it lacks knowledge

and information sufficient to form a belief as to the truth of such allegations and therefore denies the allegations contained therein.

12. In answer to paragraph 12, Bayer states that the allegations concerning FDA's actions state legal conclusions to which no response is required by Bayer. To the extent the allegations concerning FDA's actions require a response, Bayer admits that the FDA regulates over-the-counter medicines and classifies them as Category I (safe and effective), Category II (not safe and effective), or Category III (insufficient data to assess safety).

13. In answer to paragraph 13, Bayer states that the allegations concerning FDA's actions state legal conclusions to which no response is required by Bayer. To the extent the allegations concerning FDA's actions require a response, Bayer denies the allegations contained therein.

14. In answer to paragraph 14, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of the allegations asserted and therefore denies the allegations contained therein.

15. In answer to paragraph 15, Bayer denies the allegations contained therein.

16. In answer to paragraph 16, Bayer denies the allegations contained in paragraph 15 as stated. Because Plaintiffs have failed to specifically identify the published case reports or the medical literature referred to in paragraph 16, Bayer, after reasonable investigation, lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies the allegations contained therein.

17. In answer to paragraph 17, Bayer denies the allegations contained in paragraph 16 as stated. Because Plaintiffs have failed to specifically identify the published case report referred to in paragraph 16, Bayer, after reasonable investigation, lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies the allegations contained therein.

18. In answer to paragraph 18, Bayer denies the allegations contained in paragraph 18 as stated. Because Plaintiffs have failed to specifically identify the FDA report or the articles referred to in paragraph 18, Bayer, after reasonable investigation, lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies the allegations contained therein.

19. In answer to paragraph 19, Bayer denies the allegations contained in paragraph 19 as stated. Because Plaintiffs have failed to specifically identify the published case reports or the medical literature referred to in paragraph 19, Bayer, after reasonable investigation, lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies the allegations contained therein.

20. In answer to paragraph 20, Bayer states that the allegations concerning FDA's actions state a legal conclusion to which no response is required by Bayer. To the extent the allegations concerning FDA's actions require a response, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of the allegations and, therefore, denies the allegations contained therein.

21. In answer to paragraph 21, Bayer states that the allegations concerning FDA's actions state a legal conclusion to which no response is required by Bayer. To the extent

the allegations concerning FDA's actions require a response, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of the allegations and, therefore, denies the allegations contained therein.

22. In answer to paragraph 22, Bayer states that the allegations concerning FDA's actions state a legal conclusion to which no response is required by Bayer. To the extent the allegations concerning FDA's actions require a response, Bayer denies the allegations contained therein.

23. In answer to paragraph 23, Bayer denies the allegations contained in paragraph 23 as stated. Because Plaintiffs have failed to specifically identify the review article referred to in paragraph 23, Bayer, after reasonable investigation, lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies the allegations contained therein.

24. In answer to paragraph 24, Bayer admits that on September 24, 1990, hearings regarding OTC diet supplements were held before the House of Representatives Subcommittee on Regulations, Business Opportunities and Energy. As to the remaining allegations, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies the allegations contained therein.

25. In answer to paragraph 25, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies the allegations contained therein.

26. In answer to paragraph 26, Bayer denies the allegations contained in paragraph 26 as stated. Because Plaintiffs have failed to specifically identify the FDA report referred to in paragraph 26, Bayer lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies the allegations contained therein.

27. In answer to paragraph 27, Bayer states that the allegations concerning FDA's actions state legal conclusions to which no response is required by Bayer. To the extent the allegations concerning FDA's actions require a response, Bayer admits that, in 1991, the FDA held a public meeting to address the safety and effectiveness of PPA. With regard to the remaining allegations, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies said allegations.

28. In answer to paragraph 28, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of such allegations and, therefore, denies the allegations contained therein.

29. In answer to paragraph 29, Bayer denies the allegations contained therein. Furthermore, insofar as the allegations thereof suggest, imply or state that there are health risks, safety concerns and/or life threatening adverse reactions, including hypertension and stroke, associated with PPA and that Bayer knew or should have known of same, they are expressly denied.

30. In answer to paragraph 30, Bayer admits that on March 9, 1993, the FDA issued a letter to the NDMA stating that it would be classifying PPA as Category III. Except as admitted, Bayer denies the allegations contained in paragraph 30.

31. In answer to paragraph 31, Bayer denies the allegations contained therein.

32. In answer to paragraph 32, Bayer states that no allegation in paragraph 32 is directed at Bayer and, therefore, no answer is required by Bayer. To the extent an answer is deemed necessary, Bayer denies the allegations contained therein.

33. In answer to paragraph 33, Bayer admits that the Hemorrhagic Stroke Project began in September of 1994. Except as admitted, Bayer denies the allegations contained therein.

34. In answer to paragraph 34, Bayer denies the allegations contained therein.

35. In answer to paragraph 35, Bayer denies the allegations contained therein.

36. In answer to paragraph 36, Bayer admits that on December 21, 2000, the *New England Journal of Medicine* published an article entitled, "Phenylpropanolamine And The Risk Of Hemorrhagic Stroke" which speaks for itself. Except as admitted, Bayer denies the allegations contained therein.

37. In answer to paragraph 37, Bayer denies the allegations contained therein.

38. In answer to paragraph 38, Bayer denies the allegations contained therein.

39. In answer to paragraph 39, Bayer denies the allegations contained therein.

40. In answer to paragraph 40, Bayer states that the allegations concerning FDA's actions state legal conclusions to which no response is required by Bayer. To the extent the allegations concerning FDA's actions require a response, Bayer states that it lacks knowledge



and information sufficient to form a belief as to the truth of such allegations and therefore denies the allegations contained therein.

41. In answer to paragraph 41, Bayer denies the allegations contained therein.

42. In answer to paragraph 42, Bayer states that the allegations concerning FDA's actions state legal conclusions to which no response is required by Bayer. To the extent the allegations concerning FDA's actions require a response, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of such allegations and therefore denies the allegations contained therein.

43. In answer to paragraph 43, Bayer denies the allegations contained therein.

44. In answer to paragraph 44, Bayer denies the allegations contained therein.

45. In answer to paragraph 45, Bayer admits that PPA is a vasoconstrictor and was an active ingredient in *Alka-Seltzer Plus* effervescent cold medicine. As to the remaining allegations, Bayer denies the allegations contained therein.

46. In answer to paragraph 46, Bayer denies the allegations contained therein.

47. In answer to paragraph 47, Bayer denies the allegations contained therein.

48. In answer to paragraph 48, Bayer admits that at certain times, Bayer has been a member of the Non-Prescription Drug Manufacturers Association (the "NDMA") and that the NDMA is currently known as the Consumer Healthcare Products Association ("CHPA"). Except as admitted, Bayer denies the allegations contained therein.

49. In answer to paragraph 49, as directed against Bayer, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of the allegations regarding CHPA and therefore denies said allegations. In answer to the allegations directed at Bayer, Bayer denies said allegations.

50. In answer to paragraph 50, admits that prior to November 6, 2000, it manufactured, promoted, marketed and sold non-prescription, over-the-counter medicines containing PPA for use in accordance with their labeling. Furthermore, Bayer admits that its PPA-containing decongestant medicines were safe as marketed and distributed and included adequate warnings and instructions for safe use. Except as admitted, Bayer denies the remaining allegations contained in paragraph 50.

51. In answer to paragraph 51, Bayer admits that its PPA-containing decongestant medicines were safe as marketed and distributed and included adequate warnings and instructions for safe use. Except as admitted, Bayer denies the remaining allegations contained in paragraph 51.

52. In answer to paragraph 52, Bayer denies the allegations contained therein.

53. In answer to paragraph 53, Bayer denies the allegations contained therein.

54. In answer to paragraph 54, Bayer responds that to the extent paragraph 54 concerns Plaintiff, Carolyn Rollins' state of mind when she purchased PPA-containing products, Bayer lacks knowledge and information sufficient to form a belief as to the truth of the allegations asserted and therefore denies the allegations contained therein. Bayer denies the remaining allegations.

55. In answer to paragraph 55, Bayer denies any implication that Bayer engaged in any wrongdoing whatsoever. As to the remaining allegations, Bayer lacks knowledge and information sufficient to form a belief as to the truth of the allegations asserted and therefore denies the allegations contained therein.

56. In answer to paragraph 56, Bayer denies the allegations contained therein.

57. In answer to paragraph 57, Bayer incorporates by reference, as if fully set forth herein, all preceding paragraphs of this answer.

58. In answer to paragraph 58, Bayer admits that prior to November 6, 2000, it manufactured, promoted, marketed and sold non-prescription, over-the-counter medicines containing PPA for use in accordance with their labeling in Alabama and throughout the United States under the *Alka-Seltzer Plus* effervescent cold medicine brand name. With regard to whether Plaintiff, Carolyn Rollins purchased medicines containing PPA, Bayer lacks knowledge and information sufficient to form a belief as to the truth of the allegations asserted and therefore denies said allegations. Except as admitted, Bayer denies the remaining allegations.

59. In answer to paragraph 59, Bayer admits that prior to November 6, 2000, it manufactured, promoted, marketed and sold non-prescription, over-the-counter medicines containing PPA for use in accordance with their labeling in Alabama and throughout the United States under the *Alka-Seltzer Plus* effervescent cold medicine brand name. Bayer admits that it expected the medicines to reach consumers without substantial change in the condition in which they left the possession of Bayer. Except as admitted, Bayer denies the remaining allegations.

60. In answer to paragraph 60, including all of its sub-parts, Bayer denies the allegations contained therein.

61. In answer to paragraph 61, Bayer denies the allegations contained therein.

62. In answer to paragraph 62, Bayer denies any implication that it was involved in any wrongdoing. Bayer denies the remaining allegations contained therein.

In answer to the demand portion of Count One, Alabama Extended Manufacturers' Liability Doctrine, Bayer denies the allegations directed at Bayer contained therein and further denies that Plaintiffs are entitled to any of the relief requested or to any relief whatsoever of or from Bayer.

63. In answer to paragraph 63, Bayer incorporates by reference, as if fully set forth herein, all preceding paragraphs of this answer.

64. In answer to paragraph 64, Bayer denies the allegations contained therein.

65. In answer to paragraph 65, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of the allegations asserted and therefore denies the allegations contained therein.

66. In answer to paragraph 66, Bayer denies any implication that it was involved in any wrongdoing whatsoever. As to the remaining allegations, Bayer lacks knowledge and information sufficient to form a belief as to the truth of the allegations asserted and therefore denies the allegations contained therein.

67. In answer to paragraph 67, Bayer states that the allegations therein state legal conclusions to which no response is required by Bayer. To the extent an answer is deemed necessary, Bayer denies the allegations contained therein.

68. In answer to paragraph 68, Bayer states that its PPA-containing decongestant medicines were safe as marketed and distributed and included adequate warnings and instructions for safe use. With regard to Plaintiff's knowledge, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's knowledge and therefore denies said allegations.

69. In answer to paragraph 69, Bayer states that it had a duty to comply with all applicable law, which it did. Bayer denies the remaining allegations contained therein.

70. In answer to paragraph 70, Bayer denies any implication that it was involved in any wrongdoing. Bayer denies the remaining allegations contained therein.

In answer to the demand portion of Count Two, Failure to Warn, Bayer denies the allegations directed at Bayer contained therein and further denies that Plaintiff is entitled to any of the relief requested or to any relief whatsoever of or from Bayer.

71. In answer to paragraph 71, Bayer incorporates by reference, as if fully set forth herein, all preceding paragraphs of this answer.

72. In answer to paragraph 72, Bayer admits that prior to November 6, 2000, it manufactured, promoted, marketed and sold non-prescription, over-the-counter medicines containing PPA for use in accordance with their labeling in Alabama and throughout the United

States under the *Alka-Seltzer Plus* effervescent cold medicine brand name. Except as admitted, Bayer denies the remaining allegations.

73. In answer to paragraph 73, Bayer states that it lacks knowledge and information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations contained therein.

74. In answer to paragraph 74, Bayer denies the allegations contained therein.

75. In answer to paragraph 75, Bayer denies any implication that it was involved in any wrongdoing. Bayer denies the remaining allegations.

In answer to the demand portion of Count Three, Breach of Warranty of Merchantability, Bayer denies the allegations directed at Bayer contained therein and further denies that Plaintiff is entitled to any of the relief requested or to any relief whatsoever of or from Bayer.

76. In answer to paragraph 76, Bayer incorporates by reference, as if fully set forth herein, all preceding paragraphs of this answer.

77. In answer to paragraph 77, Bayer denies the allegations contained therein.

78. In answer to paragraph 78, Bayer states that the allegations therein state legal conclusions to which no response is required by Bayer. To the extent an answer is deemed necessary, Bayer states that it had a duty to comply with all applicable law, which it did. Bayer denies the remaining allegations contained therein.

79. In answer to paragraph 79, including all of its sub-parts, Bayer denies the allegations contained therein.

80. In answer to paragraph 80, Bayer denies the allegations contained therein.

81. In answer to paragraph 81, Bayer denies any implication that it was involved in any wrongdoing. Bayer denies the remaining allegations.

In answer to the demand portion of Count Four, Negligence, Bayer denies the allegations directed at Bayer contained therein and further denies that Plaintiff is entitled to any of the relief requested or to any relief whatsoever of or from Bayer.

82. In answer to paragraph 82, Bayer incorporates by reference, as if fully set forth herein, all preceding paragraphs of this answer.

83. In answer to paragraph 83, Bayer denies the allegations contained therein.

84. In answer to paragraph 84, Bayer states that the allegations state legal conclusions to which no response is required by Bayer. To the extent an answer is deemed necessary, Bayer states that it had a duty to comply with all applicable law, which it did. Bayer denies the remaining allegations contained therein.

85. In answer to paragraph 85, including all of its sub-parts, Bayer denies the allegations contained therein.

86. In answer to paragraph 86, Bayer denies the allegations contained therein.

87. In answer to paragraph 87, Bayer denies any implication that it was involved in any wrongdoing. Bayer denies the remaining allegations.

In answer to the demand portion of Count Five, Wantonness, Bayer denies the allegations directed at Bayer contained therein and further denies that Plaintiff is entitled to any of the relief requested or to any relief whatsoever of or from Bayer.

88. In answer to paragraph 88, Bayer incorporates by reference, as if fully set forth herein, all preceding paragraphs of this answer.

89. In answer to paragraph 89, Bayer denies the allegations contained therein.

90. In answer to paragraph 90, including all of its sub-parts, Bayer denies the allegations contained therein.

91. In answer to paragraph 91, Bayer denies the allegations contained therein

92. In answer to paragraph 92, Bayer denies any implication that it engaged in any wrongdoing whatsoever. Bayer denies the remaining allegations contained therein.

93. In answer to paragraph 93, Bayer denies any implication that it engaged in any wrongdoing whatsoever. Bayer denies the remaining allegations contained therein.

94. In answer to paragraph 94, Bayer denies any implication that it engaged in any wrongdoing whatsoever. Bayer denies the remaining allegations contained therein.

95. In answer to paragraph 95, Bayer states that the allegations state legal conclusions to which no response is required by Bayer. To the extent an answer is deemed necessary, Bayer states that it had a duty to comply with applicable law, which it did. Bayer denies the remaining allegations contained therein.

96. In answer to paragraph 96, Bayer denies the allegations contained therein.



97. In answer to paragraph 97, Bayer denies the allegations contained therein.

98. In answer to paragraph 98, Bayer denies any implication that it was involved in any wrongdoing. Bayer denies the remaining allegations.

In answer to the demand portion of Count Six, Fraud, Misrepresentation, and Suppression, Bayer denies the allegations directed at Bayer contained therein and further denies that Plaintiff is entitled to any of the relief requested or to any relief whatsoever of or from Bayer.

#### **RELIEF REQUESTED**

99. Except as specifically admitted and alleged herein, Bayer denies each and every allegation of Plaintiff's unverified Original Complaint and the whole thereof. Bayer further specifically denies that Plaintiff was injured, damaged, or suffered any loss as alleged, or at all, and denies that Plaintiff is entitled to any form of relief.

100. Bayer denies that Plaintiff is entitled to any of the relief requested in the prayer for relief in the complaint.

#### **AFFIRMATIVE DEFENSES**

101. Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Bayer in this matter. Bayer therefore asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Bayer may withdraw any of these affirmative defenses as may be appropriate. Further, Bayer reserves the right to amend this answer to assert additional

defenses, cross-claims, counterclaims and other claims and defenses as discovery proceeds. Further answering and by way of affirmative defense, Bayer states as follows:

FIRST AFFIRMATIVE DEFENSE  
(Failure to State a Claim)

102. Plaintiff's amended complaint and each and every purported cause of action therein fail to state facts sufficient to constitute a cause of action against Bayer.

SECOND AFFIRMATIVE DEFENSE  
(Statute of Limitations)

103. With respect to each and every cause of action in Plaintiff's amended complaint, all or part of Plaintiff's claims are barred by the applicable statute of limitations.

THIRD AFFIRMATIVE DEFENSE  
(Consent/Assumption of Risk)

104. Plaintiff, knowing the nature and properties of the medicine(s) which are the subject matter of this action, consented to use, if any, the medicine(s), and/or assumed the risk of such use, and accordingly Bayer cannot be held liable.

FOURTH AFFIRMATIVE DEFENSE  
(Preemption)

105. With respect to each and every cause of action in Plaintiff's amended complaint, the acts alleged are regulated by the statutes and regulations of the federal government, which preempt all additional or different state laws. Accordingly, the claims of Plaintiff are preempted in whole or in part by federal law pursuant to the Supremacy Clause of the United States Constitution.

FIFTH AFFIRMATIVE DEFENSE  
(Indispensable Parties)

106. Plaintiffs have failed to join indispensable parties required for a proper adjudication of this matter. Furthermore, in the alternative, the alleged injuries and/or losses of the Plaintiff, if any, were caused in part by the legal fault and/or negligence of parties other than Bayer, over whom Bayer had no control.

SIXTH AFFIRMATIVE DEFENSE  
(Improper Joinder)

107. Plaintiff's amended complaint is an improper joinder and an improper accumulation of parties.

SEVENTH AFFIRMATIVE DEFENSE  
(Privity)

108. With respect to each and every purported cause of action in Plaintiff's amended complaint, Plaintiff is barred by lack of privity with Bayer.

EIGHTH AFFIRMATIVE DEFENSE  
(Good Faith)

109. With respect to each and every purported cause of action in Plaintiff's amended complaint, the acts of Bayer were at all times done in good faith and without malice, evidenced by, among other things, Bayer's immediate withdrawal from the market of the medicine(s) which are the subject matter of this action.

NINTH AFFIRMATIVE DEFENSE  
(Conformity with Medical Knowledge)

110. With respect to each and every purported cause of action in Plaintiff's amended complaint, Bayer alleges that its methods, standards, and techniques in the preparation of the medicine(s) which are the subject matter of this action were and are in conformity with the generally recognized state of the medical knowledge, common and accepted procedure in the medical field, and state of the art at the time of their preparation.

TENTH AFFIRMATIVE DEFENSE  
(Conformity with Applicable Law)

111. With respect to each of Plaintiff's claims, all medicines(s) which are the subject matter of this action were prepared by Bayer and provided by Bayer, including their labels and packaging, pursuant to the approval of the appropriate federal agencies and applicable statutes and regulations; approval of preparation of said medicine(s) was obtained in compliance with all requirements pertaining to the preparation and/or distribution of such medicine(s) and was accomplished pursuant to acceptable standards of conduct.

ELEVENTH AFFIRMATIVE DEFENSE  
(No Duty to Warn)

112. To the extent there were any risks associated with the use of the medicine(s) which are the subject matter of this action which Bayer knew or should have known and which gave rise to a duty to warn, Bayer at all times discharged such duty through appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge. In the alternative, Bayer had no duty to warn persons directly concerning risks, if any, associated with the use of said medicine(s).

TWELFTH AFFIRMATIVE DEFENSE  
(Compliance with Applicable Regulations)

113. At all times relevant herein, any medicine(s) which are the subject matter of this action processed and distributed by Bayer in the State of Alabama or in the United States were processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further were processed and distributed in accordance with and pursuant to all applicable regulations of the federal Food and Drug Administration.

THIRTEENTH AFFIRMATIVE DEFENSE  
(Public Benefit)

114. The public interest and benefit in the availability of such medicine(s) which are the subject matter of this action preclude liability for any risks, if any, resulting from such activities, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined that there is a risk inherent in any of the medicine(s) which are the subject matter of this action, then such risk, if any, is outweighed by the benefits of the medicine(s).

FOURTEENTH AFFIRMATIVE DEFENSE  
(Protected Speech)

115. Bayer's advertisements and labeling with respect to the medicine(s) which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Alabama constitutions.

FIFTEENTH AFFIRMATIVE DEFENSE  
(No Misrepresentation)

116. Bayer denies any misrepresentation and/or fraud on its part, and/or reliance by Plaintiff and detriment to Plaintiff allegedly resulting therefrom.

SIXTEENTH AFFIRMATIVE DEFENSE  
(Puffery Not Actionable)

117. To the extent Plaintiff's claims and allegations relate to mere puffery that is not misleading to a reasonable person, such claims are not actionable.

SEVENTEENTH AFFIRMATIVE DEFENSE  
(Violation of Constitutional Rights)

118. To the extent that Plaintiff's claims are based on disgorgement of revenue/profits or based on a theory providing for liability without proof of causation, the claims violate Bayer's rights under the United States Constitution and the Alabama Constitution, and Plaintiff's claims are barred by the due process provisions of the Fifth and Fourteenth Amendments to the United States Constitution and sections of the Alabama Constitution on the ground that Bayer will not be accorded protection against multiple suits and duplicative liability and to the extent that there has been a denial of equal protection.

EIGHTEENTH AFFIRMATIVE DEFENSE  
(Unclean Hands)

119. With respect to each and every purported cause of action, Plaintiff's claims are barred by the doctrine of unclean hands.

NINETEENTH AFFIRMATIVE DEFENSE  
(Waiver and Estoppel)

120. With respect to each and every purported cause of action, Plaintiff's claims are barred by the doctrine of waiver and estoppel.

TWENTIETH AFFIRMATIVE DEFENSE  
(Laches)

121. Each and every cause of action asserted in the Plaintiff's amended complaint is barred by the doctrine of laches.

TWENTY-FIRST AFFIRMATIVE DEFENSE

122. The injuries, damages, and/or loss claimed by Plaintiff, if any, were caused in whole or in part by the acts or omissions of persons other than Bayer over whom Bayer had no control.

TWENTY-SECOND AFFIRMATIVE DEFENSE  
(Lack of Causation)

123. Bayer asserts that its conduct did not cause, proximately cause, solely cause, or solely proximately cause, the injuries and/or damages claimed by Plaintiff, if any.

TWENTY-THIRD AFFIRMATIVE DEFENSE  
(Intervening/Superseding Cause)

124. The injuries and/or damages claimed by Plaintiff, if any, resulted from an intervening and superseding cause or causes and any action on the part of Bayer was not the proximate or competent producing cause of Plaintiff's alleged injuries and/or damages, if any.

TWENTY-FOURTH AFFIRMATIVE DEFENSE  
(Unavoidable Circumstances)

125. The alleged injuries and/or damages of the Plaintiff, if any, were the result of unavoidable circumstances which could not have been prevented by anyone.

TWENTY-FIFTH AFFIRMATIVE DEFENSE  
(No Negligence)

126. Bayer denies that it is liable for actionable negligence and denies that Plaintiff was injured thereby.

TWENTY-SIXTH AFFIRMATIVE DEFENSE  
(Compensatory and General Damages Not Proper)

127. With respect to each and every cause of action, Plaintiff is not entitled to compensatory or general damages.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

128. Defendant denies that it has been guilty of any conduct which warrants the issue of punitive damages being submitted to a jury.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

129. Any award of punitive damages to Plaintiff in this case would be in violation of the constitutional safeguards provided to Defendant under the Constitution of the State of Alabama.



TWENTY-NINTH AFFIRMATIVE DEFENSE

130. Any award of punitive damages to Plaintiff in this case would be in violation of the constitutional safeguards provided to Defendant under the Constitution of the United States of America.

THIRTIETH AFFIRMATIVE DEFENSE

131. No punitive damages are warranted or allowable that would exceed comparable maximums established for criminal fines.

THIRTY-FIRST AFFIRMATIVE DEFENSE

132. Punitive damages cannot be sustained because of the lack of clarity in Alabama's standards for awarding punitive damages.

THIRTY-SECOND AFFIRMATIVE DEFENSE

133. Any claim for punitive damages, on its face and/or as applied in this case, is in violation of the Fifth Amendment to the Constitution of the United States; of the right to counsel provided by the Sixth Amendment to the Constitution of the United States; of the right to trial by jury of the Seventh Amendment to the Constitution of the United States; of the proportionality principles contained in the Eighth Amendment to the Constitution of the United States; the due process clause of the Fourteenth Amendment to the Constitution of the United States; and Article 1, Sections 1, 2, 6, 11, 13, 15, 27, and 35 of the Constitution of Alabama of 1901, and is improper under the common law and public policies of the State of Alabama and under applicable court rules and statutes for the following reasons, jointly and separately:

- (a) There are no standards provided by Alabama law for the imposition of punitive damages, and therefore, Defendant has not been put on notice and given the opportunity to anticipate punitive liability and/or the potential size of the award and to modify or conform its conduct accordingly;
- (b) The procedures to be followed would permit an award of punitive damages against Defendant upon the satisfaction of a burden of persuasion (standard of proof) less than that applicable to the imposition of criminal sanctions for equal culpability;
- (c) The procedures to be followed could permit the award of multiple punitive damages for the same act or omission;
- (d) There are no provisions or standards for clear and consistent appellate review of any award of punitive damages against Defendant under present Alabama law;
- (e) The standards of conduct upon which punitive damages are sought against this defendant are vague and ambiguous;
- (f) The procedures used by courts under Alabama law and the guidelines given by the jurors, jointly and severally, are vague and ambiguous;
- (g) The procedures used by courts under Alabama law and guidelines given to jurors, jointly and separately, are vague and ambiguous and, thus, impermissibly allow jurors broad, unlimited, and undefined power to

make determinations on their notions of what the law should be instead of what it is;

- (h) The procedures under which punitive damages are awarded and the instructions used under Alabama law, jointly and separately, are vague and ambiguous and, thus, fail to eliminate the effects of, and to guard against, impermissible juror passion;
- (i) Present Alabama law does not provide for sufficiently objective and specific standards to be used by the jury in its deliberations on whether to award punitive damages and, if so, on the amount to be awarded;
- (j) Present Alabama law does not provide a meaningful opportunity for challenging the rational basis for, and any excessiveness of, any award of punitive damages;
- (k) Present Alabama law does not provide for adequate and independent review by the trial court and the appellate court of the imposition of punitive damages by a jury or of the amount of any punitive damage awarded by a jury;
- (l) Present Alabama procedures fail to provide a constitutionally reasonable limit on the amount of any punitive damage award against this defendant;
- (m) Present Alabama procedures may permit the admission of evidence relative to punitive damages in the same proceeding during which liability is determined;

- (n) Present Alabama procedures permit the imposition of joint and several judgments against multiple co-defendants for different acts of degrees of wrongdoing or culpability;
- (o) An award of punitive damages would compensate Plaintiff for elements of damage not otherwise recognized by Alabama law.

THIRTY-THIRD AFFIRMATIVE DEFENSE

134. Plaintiff's claims for the recovery of punitive damages are barred by *Ala. Code* § 6-11-20 (1993) *et seq.*

THIRTY-FOURTH AFFIRMATIVE DEFENSE

135. Plaintiff's claims for the recovery of punitive damages are barred by *Ala. Code* § 6-11-27 (1993).

THIRTY-FIFTH AFFIRMATIVE DEFENSE

136. Plaintiff's claims for the recovery of punitive damages are in contravention of Defendant's rights under each of the following constitutional provisions:

- (a) Article I, Section 8 of the United States Constitution, as an impermissible burden on interstate commerce;
- (b) the Contracts Clause of Article 1, Section 10 of the United States Constitution;

- (c) the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution;
- (d) the Equal Protection under the laws afforded by the Fourteenth Amendment to the United States Constitution;
- (e) the constitutional prohibition against vague and overbroad laws;
- (f) the prohibition against *ex post facto* law in Article 1, Section 22 of the Alabama Constitution;
- (g) the Contracts Clause of Article 1, Section 22 of the Constitution of Alabama; and
- (h) the Due Process Clause of Article 1, Section 6 and/or 13 of the Constitution of Alabama.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

137. An award of punitive damages in the circumstances of this case would clearly be violative of Defendant's due process rights as embraced by the Fifth and Fourteenth Amendment to the United States Constitution and by the due process clause of Article 1, Section 6 and/or 13 of the Alabama Constitution, jointly and separately, as such award would constitute a deprivation of property without due process of law for the following reasons as separately stated herein.

- (a) There is no rational relationship between the punitive damage awards in Alabama and the alleged wrongfulness of a defendant's conduct and/or the compensatory damages awarded.
- (b) No rational relationship exists between the extent of punitive damages and legitimate interests to be advanced by the State of Alabama.
- (c) An award of punitive damages in this case would be penal in nature and thus, would be violative of this defendant's constitutional rights under the United States Constitution and/or the Alabama Constitution unless Defendant is granted the procedural safeguards afforded criminal defendants including but not limited to constitutional safeguards against self-incrimination and a heightened standard of proof beyond a reasonable doubt.
- (d) The award of punitive damages on the basis of vicarious liability for the conduct of others violates Defendant's constitutional rights.

#### THIRTY-SEVENTH AFFIRMATIVE DEFENSE

138. The imposition of punitive damages in this case would be in denial of Defendant's right to equal protection of the laws as guaranteed by the Fourteenth Amendment to the United States Constitution and Article 1, Sections 1, 6 and 22 of the Alabama Constitution. Specifically, this defendant is treated differently from criminal defendants which are charged for similar or identical alleged culpability. Alternatively, the absence of adequate and objective standards for guiding in the assessment of punitive damages fails to insure the equality of treatment between and among similarly situated civil defendants.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

139. The assessment of punitive damages in this action would violate the Commerce Clause of Article 1, Section 8 of the United States Constitution to the extent that such award punishes acts or omissions which have allegedly occurred solely outside of state boundaries.

THIRTY-NINTH AFFIRMATIVE DEFENSE

140. The imposition of punitive damages in this case would violate Defendant's rights under Article 1, Section 22 of the Alabama Constitution in that it would impair the contractual obligations of parties to this litigation.

FORTIETH AFFIRMATIVE DEFENSE

141. With respect to Plaintiff's demand for punitive damages, Defendant specifically incorporates by reference any and all standards or limitations regarding the determination and/or enforceability of punitive damage awards which arose in the decision of BMW of No. America v. Gore, 116 U.S. 1589 (1996)(as extended by Cooper Indus. V. Leatherman Tool Group, 2001 W.L. 501732 (U.S. May 14, 2001) and State Farm Mut. Auto. Ins. Co. v. Campbell, 123 S. Ct. 1513 (2003)).

FORTY-FIRST AFFIRMATIVE DEFENSE

142. An award of punitive damages in this case, if any, may not exceed \$250,000.00. Ala. Code § 6-11-21 (Supp. 1987); see Oliver v. Towns, 1999 WL 14675, \*6 & n.7 (Ala. Jan. 15, 1999) ("[W]e question whether Henderson [v. Ala. Power Co.], 627 So. 2d 878

(Ala. 1993), remains good law.”) (citing BMW of No. America, Inc. v. Gore, 517 U.S. 559 (1996); Henderson, 627 So. 2d at 894 (Maddox, J., concurring in part; dissenting in part); Henderson, 627 So. 2d at 903 (Houston, J., dissenting); and Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 20 n.9 (1991)). In declaring § 6-11-21 unconstitutional in Henderson, the Alabama Supreme Court acted beyond the scope of its powers and violated the separation of powers clauses of the United States Constitution and the Alabama Constitution. Accordingly, the Court’s action in Henderson was without effect, and Alabama Code § 6-11-21 applies in this case.

#### FORTY-SECOND AFFIRMATIVE DEFENSE

143. Plaintiff’s claims are barred by Plaintiff’s failure to mitigate damages.

#### FORTY-THIRD AFFIRMATIVE DEFENSE

144. To the extent that Plaintiff’s demand for punitive damages may result in multiple punitive damage awards being assessed for the same act or omission against this defendant, this award contravenes Defendant’s right to due process under the due process clause of Article 1, Section 13 of the Alabama Constitution. In addition, such awards would infringe upon Defendant’s rights against double jeopardy insured by the Fifth Amendment of the United States Constitution and/or Article 1, Section 9 of the Alabama Constitution.

#### FORTY-FOURTH AFFIRMATIVE DEFENSE

145. The procedures pursuant to which punitive damages are awarded subject civil defendants to punishment for the conduct of others through vicarious liability or through non-apportionment of damages among joint tortfeasors, in violation of the Fifth and Fourteenth



Amendments to the United States Constitution and Article I §§ I and 6 of the Alabama Constitution.

FORTY-FIFTH AFFIRMATIVE DEFENSE

146. The procedures pursuant to which punitive damages are awarded expose civil defendants to the risk of undefinable, unlimited liability unrelated to actual loss, if any, caused by their conduct, creating a chilling effect on said defendants' exercise of the right to a judicial resolution of this dispute.

FORTY-SIXTH AFFIRMATIVE DEFENSE  
(Pre-Existing Condition)

147. Bayer asserts that the injuries and/or damages alleged by Plaintiff, if any, were the result of a pre-existing condition or conditions that were unrelated to any conduct of, or medicine placed in the stream of commerce by, Bayer and/or over which Bayer had no control.

FORTY-SEVENTH AFFIRMATIVE DEFENSE  
(Act of God)

148. The injuries and/or damages alleged by Plaintiff, if any, may have been caused, in whole or in part, by operation of nature or act of God.

FORTY-EIGHTH AFFIRMATIVE DEFENSE  
(Alteration or Misuse)

149. Plaintiff's alleged injuries and/or damages, if any, were caused by the alteration, unintended use, or misuse of the medicines referred to in Plaintiff's amended complaint.

FORTY-NINTH AFFIRMATIVE DEFENSE  
(Idiosyncratic Reaction)

150. With respect to each and every cause of action, Plaintiff is not entitled to recover for an idiosyncratic reaction.

FIFTIETH AFFIRMATIVE DEFENSE  
(Contributory Negligence)

151. With respect to each and every cause of action, Plaintiff is not entitled to recover because of the doctrine of contributory negligence.

FIFTY-FIRST AFFIRMATIVE DEFENSE  
(Failure to Mitigate)

152. With respect to each and every cause of action, Plaintiff is not entitled to recover because of failure to mitigate damages.

FIFTY-SECOND AFFIRMATIVE DEFENSE  
(Intervening Negligence)

153. With respect to each and every cause of action, Plaintiff is not entitled to recover because of intervening acts and/or omissions of persons or entities other than Bayer Corporation.

FIFTY-THIRD AFFIRMATIVE DEFENSE  
(Unavoidably Unsafe)

154. With respect to each and every cause of action, Plaintiff is not entitled to recover because if the medicines were unsafe, which Bayer denies, then they were unavoidably

unsafe. The apparent benefits of the medicines exceeded any apparent risk given the scientific knowledge available and the medicines marketed.

FIFTY-FOURTH AFFIRMATIVE DEFENSE  
(General Issue)

155. Bayer pleads the general issue.

FIFTY-FIFTH AFFIRMATIVE DEFENSE  
(No Express/Implied Warranty)

156. Bayer denies making any express or implied warranties to Plaintiff or any representations of any nature, but Bayer alleges that any and all warranties that may form a basis for Plaintiff's claims were adequately disclaimed.

FIFTY-SIXTH AFFIRMATIVE DEFENSE  
(Industry Custom)

157. With respect to each and every cause of action, Bayer asserts all defenses under the Alabama Extended Manufacturer's Liability Doctrine, including but not limited to industry custom, technological feasibility, and compliance with standards and regulations.

FIFTY-SEVENTH AFFIRMATIVE DEFENSE  
(No Strict Liability)

158. With respect to each and every cause of action, Plaintiff is not entitled to recover for strict liability because Plaintiff cannot state claims sounding in strict liability because, among other things, Comments J and K to Section 402A of the Restatement (Second) of Torts relegate Plaintiff to a negligence cause of action.

FIFTY-EIGHTH AFFIRMATIVE DEFENSE  
(Failure to Identify Manufacturer)

159. With respect to each and every cause of action, Plaintiff is not entitled to relief to the extent they are unable to prove the identity of the manufacturer of the precise products used by the Plaintiff.

FIFTY-NINTH AFFIRMATIVE DEFENSE  
(Learned Intermediary Doctrine)

160. Bayer asserts the application of the learned intermediary doctrine which requires that all necessary warnings and other appropriate information be delivered by the treating physician or health care provider.

SIXTIETH AFFIRMATIVE DEFENSE  
(Fundamental Fairness)

161. With respect to each and every cause of action, Plaintiff is not entitled to recover because of the delay and the fundamental unfairness and prejudice due to the excessive delay from the date of use of the product until the filing of the amended complaint.

SIXTY-FIRST AFFIRMATIVE DEFENSE  
(Economic Loss Rule)

162. Plaintiff's causes of action are barred in whole or in part by the economic loss rule.

SIXTY-SECOND DEFENSE

163. Plaintiff's claims are barred, in whole or in part, because Plaintiffs have not sustained injury or damage as a result of the matters alleged in the amended complaint.

SIXTY-THIRD DEFENSE

164. An award of mental anguish or emotional distress damages in this case will violate Bayer's Due Process and Equal Protection rights guaranteed by the Alabama Constitution and the United States Constitution because Alabama juries are not given any rules, standards, or guidelines upon which to rely in calculating mental anguish or emotional distress damage awards.

SIXTY-FOURTH DEFENSE

165. To award Plaintiff damages for alleged mental anguish or emotional distress in the absence of any standards for the determination of mental anguish or emotional distress and/or the absence of any requirement for corroboration of objective evidence of mental anguish or emotional distress makes such an award tantamount to punitive damages. As such, Bayer avers that such an award in this case would violate both the Alabama Constitution and the United States Constitution and for the other separate and several reasons stated herein.

**AMENDMENTS**

Bayer specifically reserves the right to amend its answer by adding affirmative defenses, counterclaims, cross-claims, or by instituting third-party actions as additional facts are obtained through further investigation and discovery.

WHEREFORE, Defendant BAYER CORPORATION prays for judgment as follows:

1. That Plaintiff is not entitled to equitable relief;
2. That Plaintiff takes nothing by the amended complaint;
3. For Bayer's attorneys' fees and the costs of suit incurred herein; and
4. For such other and further relief as the Court may deem just and proper.

DATED this 15<sup>th</sup> day of June, 2005.

**JURY DEMAND**

Defendant Bayer Corporation hereby demands a trial by jury of all issues within this action.

s/Brian A. Wahl  
\_\_\_\_\_  
BRIAN A. WAHL (WAH003)  
One of the Attorneys for Defendant,  
Bayer Corporation

**OF COUNSEL:**

Bradley Arant Rose & White LLP  
Jay D St. Clair (STC001)  
One Federal Place  
1819 Fifth Avenue North  
Birmingham, Alabama 35203  
Telephone: (205) 521-8000  
Facsimile: (205) 521-8800

**CERTIFICATE OF SERVICE**

I hereby certify that on June 15, 2005, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

**COUNSEL FOR PLAINTIFF**

Leila H. Watson, Esq.  
CORY, WATSON, CROWDER & DEGARIS, P.C.  
2131 Magnolia Avenue, Suite 200  
Birmingham, AL 35205  
(205) 328-2200 (Tel.)  
(205) 324-7896 (Fax)

and I hereby certify that I have mailed by United States Postal Service the document to the following non-CM/ECF participants:

None.

Respectfully submitted,

s/ Brian A. Wahl

\_\_\_\_\_  
Brian A. Wahl

Bradley Arant Rose & White LLP

One Federal Place

1819 Fifth Avenue North

Birmingham, AL 35203-2104

Telephone: (205) 521-8000

Facsimile: (205) 521-8800

E-mail: bwahl@bradleyarant.com